

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wright, Jeffrey L.C.
Appln. No. : 09/385,834
Filed: : August 3, 1999
Title : A Nutritional Supplement for Lowering Serum
Triglyceride and Cholesterol Levels

Grp./A.U. : 1616
Examiner : Sabiha Naim Qazi

Docket No. : 78691

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4.18.02

Assistant Commissioner for Patents
Washington, D.C. 20231

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SUMMARY OF INTERVIEW PURSUANT TO 37 CFR §1.133(b)

An interview concerning the above-identified application was conducted with Examiner Qazi by David Schwartz (Reg. No. 48,211) and Stephen Ewart Ph.D. on April 12, 2002.

The draft response to the Final Office Action of December 17, 2001, submitted on April 4, 2002, was discussed. The Examiner indicated that she did not have a copy of the draft amendment available for the interview but would hear Applicant's submissions. The Examiner indicated that the art in this field is crowded, and that Applicant should therefore provide evidence of the surprisingly utility of Applicant's claimed nutritional supplements.

Applicant first pointed out the proposed amendment to claim 1, wherein the omega-3 fatty acid is selected from the group consisting of eicosapentaenoic acid 20:5 ω 3 (EPA), docosahexaenoic acid 22:6 ω 3 (DHA) and stearidonic acid 18:4 ω 3 (SA).

Applicant pointed out that Burdick *et al.* (EP 1,004,594) and Novak Egon (WO 00/04887) cited in the Final Office Action are not prior art because they were published after the filing date of the instant application.

Applicant noted that the Miettinen *et al.* reference is concerned only with the solubility of the plant sterol, and that the vegetable oil fatty acid moiety is provided merely to increase solubility. There is no teaching or suggestion to use DHA, EPA or SA as the fatty acid.

Leaf *et al.*, who discuss omega-3 fatty acids in fish oils, do not teach or suggest making sterol esters of omega-3 fatty acids. The Examiner stated that the prior art shows that omega-3 fatty acids from fish oils have a cholesterol-lowering activity. Applicant stated that Leaf *et al.*, cite studies concluding that omega-3 fatty acids also may reduce serum cholesterol levels, but recognize that the reports in the literature are inconsistent, and that further study is needed.

Applicant referred the Examiner to Harris (1989) J. Lipid Res. 30:785-807, discussed in the specification, who concluded that fish oil consumption results either in no change in serum cholesterol, or actually leads to an increase in cholesterol level. This contradicts the Examiner's statement that fish oils are known to lower cholesterol levels.

Therefore, it would not be expected that a sterol ester of DHA, EPA, or SA would lower cholesterol levels, and particularly not both cholesterol and triglyceride levels. Instead, this skilled person would assume that the omega-3 fatty acid would negate the cholesterol-lowering effect of the sterol.

The Examiner again stated that there was a need for a showing of unexpected results of Applicant's claimed invention.


Applicant referred the Examiner to the Declaration of Dr. Ewart filed on April 12, 2001. Dr. Ewart's declaration describes and includes data from experiments demonstrating that Applicant's claimed nutritional supplements are effective to lower both cholesterol and triglyceride levels in the blood of an guinea pigs.

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The Examiner indicated that she would review the Harris reference and also the Declaration of Dr. Ewart, and asked Applicant to file Applicant's amendment by fax.

Respectfully submitted,

BY



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Date: April 15, 2002